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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,161	03/12/2004	Rebecca M. Cade	31089USCIP	9021
22847	7590	03/20/2006	EXAMINER	
SYNGENTA BIOTECHNOLOGY, INC. PATENT DEPARTMENT 3054 CORNWALLIS ROAD P.O. BOX 12257 RESEARCH TRIANGLE PARK, NC 27709-2257			KUBELIK, ANNE R	
			ART UNIT	PAPER NUMBER
			1638	
DATE MAILED: 03/20/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/800,161	CADE ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) 1 and 5-10 is/are allowed.
- 6) Claim(s) 11 and 13-21 is/are rejected.
- 7) Claim(s) 2-4 and 12 is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. ____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input checked="" type="checkbox"/> Other: <u>search results</u> .

DETAILED ACTION

1. Claims 1-21 are pending.
2. The title of the invention is not descriptive of the instant invention; the title should indicate what induces the promoter and its source. A new title is required that is clearly indicative of the invention to which the claims are directed. Note that titles can be up to 500 characters long.

Claim Objections

3. Claims 2-4 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The promoters of SEQ ID NO:26 and 28 inherently are induced by a SAR-induction chemical or a pathogen; thus, the claims fail to further limit parent claim 1.
4. Claim 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. SEQ ID NOs:25-27 are all overlapping portions of SEQ ID NO:24. Thus, a fragment comprising all of SEQ ID NOs:25-27 is broader than SEQ ID No:24 itself, because it would contain the portions SEQ ID NO:26 and SEQ ID NO:27 twice.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 11 and 13-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for promoters of SEQ ID NO:24-28, does not reasonably provide enablement for a promoter of any fragment of SEQ ID NO:24. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are broadly drawn to promoters comprising fragments of any size of SEQ ID NO:24, chimeric genes comprising the promoters, and vectors, plant cells, plants and seeds comprising the chimeric genes.

The instant specification, however, only provides guidance for fragments of SEQ ID NO:s 25-27.

DNA fragment of a promoter cannot predictably be assumed to also have promoter activity. Deletion analysis of various promoters have shown that even DNA segments from the portion of a promoter region containing sequence elements thought to be most important (*e.g.*, the TATA-box) need to be longer expected. Maiti et al (1997, *Transgen. Res.*, 6:143-156), in studies on a figwort mosaic virus promoter, found that smallest portion upstream of the transcriptional start site of that would support transcription was 198 basepairs long; segments of 73 and 37 basepairs did not work (Fig. 4).

Identification of the functional parts of promoters is unpredictable. Chen et al (2000, *Sex. Plant Reprod.* 13:85-94) teach that two promoters with similar expression patterns have

major differences in the expression elements required for expression in various flower parts (pg 92, right column, last two paragraphs).

The region of a given promoter that has a specific activity cannot be predicted and involves the complex interaction of different subdomains (Benfrey et al, 1990, Science 250:959-966, see Abstract, Fig. 3-5). Even a very small region may be critical for activity, and the criticality of a particular region must be determined empirically (Kim et al, 1994, Plant Mol. Biol. 24:105-117, Tables 1-4, Abstract, Fig. 1-2).

The specification does not teach how to promoter fragments that are not pathogen or SAR-induction chemical inducible.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate promoters comprising fragments of any size of SEQ ID NO:24.

Given the claim breath, unpredictability in the art, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

7. Claims 11 and 13-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to promoters comprising fragments of any size of SEQ ID NO:24. SEQ ID NO:24 is not known in the art nor are fragments of it that have promoter

activity. The specification does not describe any motifs that confer promoter activity to SEQ ID NO:24. The only species reduced to practice are SEQ ID NOs:25-27, the smallest of which is more than a quarter of the size of SEQ ID NO:24. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, one of skill in the art would not recognize that Applicant was in possession of the necessary common attributes or features of the genus in view of the disclosed species.

Hence, Applicant has not, in fact, described promoters comprising fragments of any size of SEQ ID NO:24 within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 11 and 13-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Ryals et al (1997, US Patent 5,689,044).

Ryals et al teach the PR-1 promoter, which is inducible by salicylic acid and the pathogen *P. syringae*. Ryals et al also teach chimeric genes comprising the promoter, and vectors, plant cells, plants and seeds comprising the chimeric gene (column 101, line 55, to column 103, line 4; column 139, line 15, -column 140, line 17). The PR-1 promoter comprises a fragment of at least two nucleotides of SEQ ID NO:24.

11. Claims 1-10 are free of the prior art, given the failure of the prior art to teach or suggest a promoter of SEQ ID NO:24. The closest prior art is taught by Sato et al (1997, DNA Res. 4:215-230), who teach a nucleic acid with 93.8% identity to SEQ ID NO:24 (see search results).

12. Claims 1 and 5-10 are allowable.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also

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enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne Kubelik, Ph.D.
January 10, 2006



A handwritten signature in black ink, appearing to read "Anne Kubelik".

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER